

CLAIMS

A1 26. ✓

A fast dissolving composition for pharmaceutical, veterinary, food, dietetic, or cosmetic use, comprising 1% to 50% by weight of one or more active ingredients, 50% to 99% by weight of a carrier comprising one or more polymers, optionally one or more diluents and optionally one or more additives, in particular a flavoring or a coloring, the composition being characterized in that it has a fast-dissolving isotropic microporous expanded structure and the polymers being chosen from the group consisting of polymers of plant origin, optionally in combination with polymers of animal origin or synthetic polymers, and the carrier being such that the binding polymer(s) are present in the composition in a proportion greater than or equal to 1% (w/w) and more particularly of between 6% and 98% (w/w) and in that it is capable of being obtained by the method comprising the steps of:

- homogenizing a pasty formulation comprising the active ingredient(s), the polymer(s), optionally the additives(s) and the diluents,
- injecting into a molding component,
- simultaneous drying a molding by a microwave or high-frequency type method with a vacuum level of between 30 and 700 x 10² Pa.

27. ✓

The composition of claim 26, wherein the polymer of plant origin is selected from polysaccharides obtained by chemical or enzymatic hydrolysis of chemically modified starch, polymers of a chemically modified cellulosic type, and polymers of a gum type, or mixtures thereof.

28. ✓

The composition of claim 27, wherein the polysaccharide is selected from maltodextrins or glucose syrups, and sodium glycolates of starch and mixtures thereof.

29. ✓ The composition of claim 28, wherein the polymer of plant origin is selected from maltodextrins and glucose syrups having a dextrose equivalent (DE) level of between 3 and 50 and preferably between 6 and 34, and mixtures thereof.

30. ✓ The composition of claim 27, wherein the polymer of plant origin of the cellulosic type is selected from carboxymethyl cellulose sodium of low or medium viscosity, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose and mixtures thereof.

31. ✓ The composition of claim 27, wherein the polymer of plant origin is of the guar gum, gum arabic, xanthane, pectin and alginate type, or mixtures thereof.

32. ✓ The composition of claim 26, wherein the synthetic polymer is polyvinylpyrrolidone.

33. ✓ The composition of claim 26, wherein the polymer of animal origin is selected from sodium caseinates, chitosan, their water-soluble hydrolysis derivatives, gelatin, collagen, chondroitin acid sulfate, hydrolysates thereof, and mixtures thereof.

34. ✓ The composition of claim 26, wherein the polymer(s) is/are present in the formulation at a percentage at least equal to 1% (w/w) and more particularly between 6% and 98% (w/w), and compatible with a viscosity of between 100 mPa.s and 100,000 mPa.s.

35. ✓ The composition of claim 34, wherein the polymer(s) are present in the formulation at a percentage at least equal to 1% (w/w) and more particularly between 6 and 98% (w/w), and compatible with a viscosity of between 100 mPa.s and 50,000 mPa.s.

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36. ✓

The composition of claim 26, wherein the optional diluent is selected from mannitol, sucrose, lactose, fructose, sorbitol, xylitol, maltitol and dicalcium phosphate dihydrate.

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37.

The composition of claim 26, wherein the density is less than 0.9 g/cm³.

38.

The composition of claim 37, wherein the density is between 0.2 and 0.7 g/cm³.

39.

The composition of claim 26, wherein the composition has a disintegration time of less than 1 minute, preferably 30 seconds, under conditions of use on direct contact with a mucous membrane, in particular the buccal mucous membrane, or in an appropriate volume of water.

40.

The composition of claim 26, wherein the active ingredient(s) in the isotropic expanded microporous matrix are in the dissolved or dispersed state or in film-coated forms.

41. ✓

The composition of claim 40, wherein the active ingredient(s) are selected, without limitation, from analgesics, antimigraines, antipyretic analgesics and/or anti-inflammatory agents, local anesthetics, antianginals, anticholinergic antispasmodics, antisecretory agents, muscle relaxants, antinauseants, and central and peripheral vasodilators.

42. ✓

The composition of claim 41, wherein the active ingredient is selected from the group consisting of milnacipran, piroxicam, phloroglucinol, and domperidone.

43.

The composition of claim 26, wherein the final packaging serving as the molding component is of the polypropylene type.

44.

The composition of claim 26, wherein the final packaging is of the polytetrafluoroethylene type (e.g.: Teflon®).

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45.

A process for preparing a fast-dissolving composition for pharmaceutical, veterinary, food, dietetic, or cosmetic use as claimed in claim 26, wherein a pasty formulation comprising one or more active ingredients, one or more polymers, optionally one or more additives, and one or more diluents is homogenized; the formulation is injected into a molding component, and then drying and molding are carried out simultaneously by a microwave or high frequency type process with a vacuum level of between 30 and 700×10^2 Pa, and preferably between 60 and 500×10^2 Pa (30 and 700 mbar and preferably between 60 and 500 mbar) to give rise to an isotropic microporous expanded structure of regular form, in particular having a density of less than 0.9 g/cm^3 .

46.

The process of claim 45, wherein the pasty formulation obtained by homogenization has a viscosity of between 100 mPa.s and $100,000 \text{ mPa.s}$, preferably between 100 mPa.s and $50,000 \text{ mPa.s}$, followed by injection or extrusion of the formulation into the final packaging.

47.

The process of claim 45, wherein the temperatures during the drying and forming phase are between 25°C and 80°C , thereby avoiding the degradation of the heat-labile active ingredients.

48.

The process of claim 45, wherein the drying and forming operations are simultaneous and are less than 1 hour in duration, preferably 30 minutes.

49.

The process of claim 45, wherein the component in which the simultaneous drying-molding is carried out is the final packaging.

50.

The process of claim 45, wherein the process of production is carried out continuously.